

## REMARKS

### Response to Claim Rejections – 35 USC §102

A single reference must present each element to establish a prime facie case of anticipation. Reference is made to M.P.E.P. §2131:

TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. In *re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Note that, in some circumstances, it is permissible to use multiple references in a 35 U.S.C. 102 rejection. See MPEP §2131.01

Anticipation under section 102(e) requires an identical description of the claimed invention in the reference disclosure. “There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *Scripps Clinic & Research Found. V. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed.Cir. 1991) (emphasis added).

The Official Action rejected claims 1, 2 and 3 as being anticipated by Dobak. Claim 1 is an independent claim. Claims 2 and 3 depend on claim 1. As amended, claim 1 recites that “said heat exchange catheter is *advanced into a central venous vein* of said patient” (emphasis added). As disclosed in the specification, a heat exchange catheter is placed in the central venous system of a stroke patient for treating the stroke condition. (See Application,

p 3.) The applied Dobak reference discloses *selective organ* heat transfer (emphasis added) rather than systemic heat transfer. "Due to the problems associated with total body hypothermia, attempts have been made to provide more selective cooling." Dobak, col. 2, ll. 9-11. Also, "a practical method and apparatus which modifies and controls the temperature of a selected organ satisfies a long-felt need." Dobak, col. 2, ll. 65-67.

Because Dobak does not disclose a method for systemic hypothermia, it does not anticipate claim 1 as amended. Neither does Dobak anticipate dependent claims 2 and 3.

### **Response to Claim Rejections – 35 USC §103**

To establish a prima facie case of obviousness, all the claim limitations must be taught by the prior art and there must be some suggestion or motivation for the combination of references. Reference is made to MPEP §2142:

#### **ESTABLISHING A PRIMA FACIE CASE OF OBVIOUSNESS**

"To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP §2143 §2143.03 for decisions pertinent to each of these criteria.

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the

teachings of the references.” Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). See MPEP §2144 §2144.09 for examples of reasoning supporting obviousness rejections.”

The rejection of claim 4 is based on the combination of Dobak and Dato. Claim 4 is canceled without prejudice. However, applicant would like respectfully to point out that there is no teaching, suggestion or motivation for the combination of Dobak and Dato as required by the foregoing standard presented in MPEP §2142. In Dobak, reference is made to the Dato reference in which Dobak states “[h]owever, use of the Dato device implicates the *negative effects* of total body hypothermia described above. Due to the problems associated with total body hypothermia, attempts have been made to provide more selective cooling” (emphasis added). Dobak, col. 2. ll. 7-11. Clearly, Dobak teaches away from combining its teachings with that disclosed in Dato. Hence combining the two references of Dobak and Dato would not be proper. As set forth in the MPEP, a prima facie case of obviousness therefore cannot be founded in Dobak or Dato.

In view of the amendments and the foregoing presentation relying heavily on the standards set forth in the MPEP, the application is believed to be properly formed and the claims patentable. Consequently, a notice of allowance is earnestly solicited.

Respectfully submitted,

Dated: 20 December 2001

By: Arlyn L. Alonzo  
Arlyn L. Alonzo  
Reg. No. 44,502

ALSIUS CORPORATION  
15770 Laguna Canyon Road, Suite 150  
Irvine, CA 92618  
(949) 453-0150 ext 146



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**VERSION WITH MARKINGS**

1. (Amended) A method for treating stroke patients, comprising the acts of:  
identifying a stroke patient for treatment;  
advancing a heat exchange catheter into said patient wherein said heat exchange catheter is advanced into a central venous vein of said patient; and  
inducing hypothermia using said heat exchange catheter.

45. (New) The method of claim 1 wherein the heat exchange catheter comprises  
at least one substantially elongate structure configured for establishing central venous  
access, said structure having a proximal portion and a distal portion and defining a plurality  
of lumens in communication with the exterior of the structure at said proximal and distal  
portions.

46. (New) The method of claim 1 wherein the heat exchange catheter comprises  
an elongate structure;  
a heat exchange balloon portion along said elongate structure, said structure further  
defining a plurality of heat exchange fluid flow lumens in communication with said heat  
exchange balloon portion, said heat exchange fluid flow lumens providing a path for  
circulation of heat exchange fluid from the exterior of the structure at said proximal end  
through said heat exchange balloon portion.

47. (New) The method of claim 1 wherein the heat exchange catheter comprises  
an elongate structure;  
at least one holding anchor engaged with the exterior of the elongate structure and  
including structure adapted to suturably affix the elongate structure to the patient.

48. (New) A method for treating stroke patients, comprising the acts of:  
identifying a stroke patient for treatment;  
advancing a heat exchange catheter into said patient wherein said heat exchange  
catheter is advanced into a central venous vein of said patient;  
inducing hypothermia using said heat exchange catheter;  
wherein the heat exchange catheter comprises

at least one substantially elongate structure adapted for use as a central venous catheter and configured for establishing central venous access, said structure having a proximal portion and a distal portion and defining a plurality of lumens in communication with the exterior of the structure at said proximal and distal portions;

a heat exchange balloon portion along said elongate structure, said structure further defining a plurality of heat exchange fluid flow lumens in communication with said heat exchange balloon portion, said heat exchange fluid flow lumens providing a path for circulation of heat exchange fluid from the exterior of the structure at said proximal end through said heat exchange balloon portion; and

at least one anchor suture engaged with the exterior of the elongate structure and including structure adapted to suturably affix the elongate structure to the patient.